REMARKS

In the final Office Action dated May 14, 2009, claim 1 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claims 1 and 2 are rejected under 35 U.S.C. § 103 as being unpatentable over Wright in view of Levin et al. Claim 4 is rejected under 35 U.S.C. § 103 as being unpatentable over Wright in view of Levin et al. in further view of Corday et al, or Hall et al. or Smits. With this Amendment, claim 1 is amended. After entry of this Amendment, claims 1, 2 and 4 are pending in the Application.

Claim 1 has been amended to recite a device for infusion therapy comprising a balloon catheter, a guide wire to be inserted into a guide lumen of the balloon catheter, pulsation detection means for detecting pulsation of the heart and stroke means for causing the guide wire to stroke in synchronization with the pulsation of the heart based on a detection signal of the pulsation detection means. The balloon catheter is inserted into a blood vessel and has a plurality of lumens extending along an axis that are formed in one catheter body, and has two expandable balloons expanding in a direction perpendicular to the axis of the catheter body are arranged axially in series. When inserted, the balloons are adjusted so that a blood vessel area surrounding the lesion is placed between the two balloons. The plurality of lumens comprises an infusion lumen that has an infusion hole communicating with an outside of the catheter body between said two balloons, and can supply drugs, cells, a treatment instrument, or the like to the outside of the catheter body through said infusion hole; balloon lumens that communicate with insides of said two balloons to control expansion of said balloons; and a bypass lumen that communicates with the outside of the catheter body with bypass holes in both a position distal the two balloons and proximal a tip of the catheter, which is on each side of said two balloons, and bypasses an occluded area formed by the two balloons to allow blood flow, wherein the bypass lumen is also a guide lumen into which the guide wire that guides the catheter body to a target position is inserted, wherein when in the targeted position, the guide wire is partially removed from the guide lumen to a position distal the bypass holes to allow for the bypass lumen.

Claim 1 has been amended to recite that the balloons are along the axis of the

catheter in series rather than in parallel to correct the claim and reflect the two balloons clearly shown in the figures. The claim has also been clarified to recite that the balloons are inflated in a direction perpendicular to the axis rather than outside, to more accurately recite the claimed device. The claim is also amended to clarify that the bypass lumen and the guide lumen are one and the same. This is clearly described in the specification in paragraphs [0042] – [0044] and shown in the figures. The bypass holes are described as being on each side of the two balloons. In other words, the holes are proximal the tip 1a of the catheter and distal the two balloons. As stated in the specification in paragraph [0034], bypass hole 14 is in a position closer to the tail end 1b than the two balloons, that is, in a distal position.

Applicants respectfully submit that these changes to not change the scope of the claim by clarify the claim so that the §112, second paragraph rejection is overcome.

Claims 1 and 2 are rejected under 35 U.S.C. § 103 as being unpatentable over Wright in view of Levin et al. Claim 1 recites balloon lumens that communicate with insides of said two balloons to control expansion of said balloons. Each balloon having its own lumen allows for the balloons to be inflated separately and to different diameters to occlude blood vessels with varying sizes without damage. Support for this can be found in the specification, for example, in paragraph [0038] and clearly shown in Fig. 1. Neither Wright nor Levin teaches, suggests or renders obvious the use of a lumen for each balloon so that the balloons can be inflated to different diameters.

Claim 1 also recites stroke means for causing the guide wire to stroke in synchronization with the pulsation of the heart based on a detection signal of the pulsation detection means. The Examiner contends that Levin discloses means for moving in a back and forth stroke in synchronization with the pulsation of the heart. Levin actually discloses a catheter loop 48 that is biased against the walls of the artery and works in conjunction with the telescopic design of the catheter tip 11 to follow the contraction and expansion of the aorta, acting as a spring. Col. 8, lines 44-58. This is a reactive design that moves as the blood moves. Levin does not disclose stroke means connected to the guide wire to move the guide wire only. As noted by the Examiner, Wright does not disclose stroke means. Wright

discloses bypassing blood. Wright also discloses the use of a pump to control the pumping rates of the slurry. The pump in Wright has nothing to do with the flow of bypass blood. If the telescopic catheter tip and catheter loop of Levin are combined with the catheter of Wright, the catheter of Wright would react in a "spring-like" manner as does Levin. The guide wire within Wright would not be moved in and out based on the stroke of the heart to adjust the bypass flow as recited in Applicants' claim. Furthermore, moving the tip of the catheter may displace the balloons that surround the injection sight, thereby rendering the device inoperable. Neither Wright nor Levin disclose a stroke means that moves the guide wire.

Claim 1 also recites that the balloon catheter is previously combined with the guide wire before insertion into the blood vessel. Wright discloses that the guide wire is inserted into the artery or other vessel, followed with X-ray visualization techniques and then the catheter is guided over and along the wire. Col. 3, line 65-col. 4, line 1. Levin discloses that an introducer catheter 19 in introduced to the body. A flexible guide wire 20 can be used to facilitate entry of the catheter tip. The guide wire is threaded through a lumen after the introducer catheter is in place. Col. 8, line 31-40. The guide wire is not a necessary component of the device of Levin. Neither Wright nor Levin teach, suggest or render obvious introducing the guide wire and the catheter simultaneously as recited in the claim.

For at least these reasons, Wright in view of Levin does not teach, suggest or render obvious the device recited in claim 1. Applicant respectfully submits that claim 1 is in condition for allowance, notice of which is requested.

Claim 2 depends from claim 1 to include all of the limitations therein. For at least this reason, claim 2 is not taught, suggested or rendered obvious by the cited references. Claim 2 is also in condition for allowance, notice of which is requested.

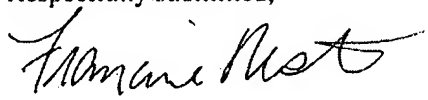
Claim 4 is rejected under 35 U.S.C. § 103 as being unpatentable over Wright in view of Levin et al. in further view of Corday et al, or Hall et al. or Smits. Claim 4 depends from claim 1 to include all of the limitations therein. Corday et al, Hall et al and Smits all fail to teach, suggest or render obvious, alone or in combination, a lumen for each balloon. Due to its dependency, claim 4 is also not taught, suggested or rendered obvious by

the combinations presented by the Examiner. For this reason at least, Applicant submits that claim 4 is in condition for allowance, notice of which is requested.

It is further submitted that this Amendment has antecedent basis in the application as originally filed, including the specification, claims and drawings, and that this Amendment does not add any new subject matter to the application. Reconsideration of the application as amended is requested. It is respectfully submitted that this Amendment places the application in suitable condition for allowance; notice of which is requested.

If the Examiner feels that prosecution of the present application can be expedited by way of an Examiner's amendment, the Examiner is invited to contact the Applicant's attorney at the telephone number listed below.

Respectfully submitted,



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